For Immediate Release:	Monday, August 04, 2008
Contact:	CMS Office of Public Affairs 202-690-6145

CMS IMPROVES PATIENT SAFETY FOR MEDICARE AND MEDICAID BY ADDRESSING NEVER EVENTS

Overview:

On July 31, 2008, the Centers for Medicare & Medicaid Services (CMS) announced new Medicare and Medicaid payment and coverage policies to improve safety for hospitalized patients. The Inpatient Prospective Payment System (IPPS) FY 2009 final rule expands the list of selected hospital-acquired conditions (HACs) that will have Medicare payment implications beginning October 1, 2008. In addition, CMS has announced the initiation of three Medicare National Coverage Determinations (NCD) proceedings for "wrong surgery," a category of "never events" included in the National Quality Forum's (NQF's) list of Serious Reportable Adverse Events. Further, the Agency has issued a State Medicaid Director (SMD) letter outlining the authority of State Medicaid Agencies to deny payment for selected hospital-acquired conditions.

These patient safety policies are part of CMS' efforts to promote higher quality, more efficient health care through value-based purchasing (VBP). VBP initiatives use performance-based financial incentives and public reporting of quality information to encourage improvement in all aspects of quality, including patient safety. CMS' transformation of its public payer role into that of an active purchaser responds to the President's Executive Order: Promoting Quality and Efficient Health Care in Federal Government (http://www.whitehouse.gov/news/releases/2006/08/20060822-2.html) and the four cornerstones of the Secretary of the Department of Health and Human Services' Value-driven Health Care initiative (http://www.hhs.gov/valuedriven).

In the IPPS FY 2009 final rule, CMS also announced enhancements, including the addition of 13 new measures, to another hospital VBP initiative, the Reporting Hospital Quality Data for the Annual Payment Update program (hospital pay for reporting). More information about

the additional quality measures is available at: www.cms.hhs.gov/apps/media/fact_sheets.asp.

Expansion of the HAC List for FY 2009

Section 5001(c) of the Deficit Reduction Act of 2005 (DRA) authorized the Secretary of the Department of Health and Human Services to select conditions that: (1) are high cost, high volume, or both; (2) are identified through ICD-9-CM coding as complicating conditions (CCs) or major complicating conditions (MCCs) that, when present as secondary diagnoses on claims, result in a higher-paying MS-DRG; and (3) are reasonably preventable through the application of evidence-based guidelines. The Agency required hospitals to begin reporting for discharges on or after October 1, 2007, whether the diagnoses for selected conditions listed on claims were present on admission (POA). In the IPPS FY 2008 final rule, CMS selected eight categories of conditions for the HAC provision, and in the IPPS FY 2009 proposed rule, CMS identified nine additional categories of candidate conditions.

In the IPPS FY 2009 final rule, CMS added several conditions to those eight selected during IPPS FY 2008 rulemaking (see Table 1). All of the conditions will have payment implications when acquired during an inpatient stay beginning with discharges on or after October 1, 2008. The additional conditions are: 1) surgical site infections following certain orthopedic procedures and bariatric surgery for obesity; 2) manifestations of poor blood sugar control, such as diabetic ketoacidosis and hypoglycemic coma; and 3) deep vein thrombosis or pulmonary embolism associated with total knee and hip replacement procedures.

CMS' selected HACs address several of the events on the NQF's list of Serious Reportable Adverse Events, commonly referred to as "never events" (see Table 2). CMS' HACs were selected according to the DRA statutory criteria indicated above. NQF's 28 events were selected according to the following criteria: (1) unambiguous, (2) usually preventable, (3) serious, (4) indicative of a safety system problem, and (5) important for public accountability. Because the CMS selection criteria for HACs and the NQF selection criteria are similar, but not the same, the conditions selected for each overlap,

but are not identical. CMS' HACs overlap with eight of the events on the NQF's list. Separately, CMS is applying Medicare's national coverage policy to address the "wrong surgery" category of conditions on the NQF's list (see description below).

More information on CMS' HAC & POA initiative is available at:

www.cms.hhs.gov/HospitalAcqCond.

Addressing Wrong Surgery through Medicare National Coverage Policy

Section 1862(a)(1)(A) of the Social Security Act requires CMS to deny payment for a particular item or service that is not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body part. CMS will use its NCD process to establish coverage policies for surgery on the wrong body part, surgery on the wrong patient, and wrong surgery performed on a patient. After a 30-day comment period on the proposed decision, if CMS decides that any of the above surgeries are not reasonable and necessary, CMS will no longer pay for hospital and physician services that correspond to these surgeries.

More information is available at:

https://www.cms.hhs.gov/mcd/viewnca.asp?where=index&nca_id=223&basket=nca:00401N:223:Wrong+Surgery+Performed+on+a+Patient:Open:New:1

https://www.cms.hhs.gov/mcd/viewnca.asp?where=index&nca_id=222&basket=nca:00402N:222:Surgery+on+the+Wrong+Body+Part:Open:New:1

https://www.cms.hhs.gov/mcd/viewnca.asp?where=index&nca_id=221&basket=nca:00403N:221:Surgery+on+the+Wrong+Patient:Open:New:1

Aligning Medicare and Medicaid Patient Safety Initiatives

CMS periodically issues letters to SMDs addressing Medicaid policy issues. CMS is issuing an SMD letter advising that, when Medicare does not pay a hospital the higher MS-DRG amount because of an HAC, State Medicaid Agencies can coordinate with CMS to similarly avoid payment liability. Moreover, CMS and States are equally concerned that such non-payment practices apply to improper patient care provided to the Medicaid-only population. A State wishing to avoid Medicaid payment liability on HACs may do so by including a general statement in its section 4.19A of the Medicaid State plan governing inpatient hospital reimbursement indicating the State's payment policy in such circumstances. Additional information on the required information for a Medicaid State Plan amendment can be found at http://www.cms.hhs.gov/smdl.

The SMD letter is available at:

www.cms.hhs.gov/SMDL/SMD/list.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=descending&intNumPerPage=10

Table 1

Hospital-Acquired Conditions for FY 2009

Selected HAC	CC/MCC (ICD-9-CM Codes)
Foreign Object Retained After Surgery	998.4 (CC) 998.7 (CC)
Air Embolism	999.1 (MCC)
Blood Incompatibility	999.6 (CC)
Pressure Ulcer Stages III & IV	707.23 (MCC) 707.24 (MCC)
Falls and Trauma: - Fracture - Dislocation - Intracranial Injury - Crushing Injury - Burn - Electric Shock	Codes within these ranges on the CC/MCC list: 800-829 830-839 850-854 925-929 940-949 991-994
Catheter-Associated Urinary Tract Infection (UTI)	996.64 (CC) Also excludes the following from acting as a CC/MCC: 112.2 (CC) 590.10 (CC) 590.11 (MCC) 590.2 (MCC) 590.3 (CC) 590.80 (CC)

Selected HAC	CC/MCC (ICD-9-CM Codes)
	590.81 (CC) 595.0 (CC) 597.0 (CC) 599.0 (CC)
Vascular Catheter-Associated Infection	999.31 (CC)
Manifestations of Poor Glycemic Control	250.10-250.13 (MCC) 250.20-250.23 (MCC) 251.0 (CC) 249.10-249.11 (MCC) 249.20-249.21 (MCC)

Surgical Site Infection, Mediastinitis, Following Coronary Artery Bypass Graft (CABG)	519.2 (MCC) And one of the following procedure codes: 36.10–36.19
Surgical Site Infection Following Certain Orthopedic Procedures	996.67 (CC) 998.59 (CC) And one of the following procedure codes: 81.01-81.08, 81.23-81.24, 81.31-81.38, 81.83, or 81.85
Surgical Site Infection Following Bariatric Surgery for Obesity	*Principal Diagnosis* – 278.01 998.59 9 (CC) And one of the following

	procedure codes: 44.38, 44.39, 44.95
Deep Vein Thrombosis and Pulmonary Embolism Following Certain Orthopedic Procedures	415.11 (MCC) 415.19 (MCC) 453.40-453.42 (MCC) And one of the following procedure codes: 00.85-00.87, 81.51-81.52, 81.54

Table 2

Patient Safety: CMS Initiatives Addressing Never Events

Current NQF Serious Reportable Adverse Events	**CMS VBP Efforts**
Surgical Events	
Surgery on wrong body part	National Coverage Determination
Surgery on wrong patient	National Coverage Determination
Wrong surgery on a patient	National Coverage Determination
Foreign object left in patient after surgery	Hospital-Acquired Condition
Post-operative death in normal health patient	
Implantation of wrong egg	
Product or Device Events	

Death/disability associated with use of contaminated drugs	
Death/disability associated with use of device other than as intended	
Death/disability associated with intravascular air embolism	Hospital-Acquired Condition
Patient Protection Events	
Infant discharged to wrong person	
Death/disability due to patient elopement	
Patient suicide or attempted suicide resulting in disability	
Care Management Events	
Death/disability associated with medication error	
Death/disability associated with incompatible blood	Hospital-Acquired Condition
Maternal death/disability with low risk delivery	
Death/disability associated with hypoglycemia	Hospital-Acquired Condition
Death/disability associated with hyperbilirubinemia in neonates	
Stage 3 or 4 pressure ulcers after admission	Hospital-Acquired Condition
Death/disability due to spinal manipulative therapy	
Environment Events	
Death/disability associated with electric shock	Hospital-Acquired Condition
Incident due to wrong oxygen or other gas	
Death/disability associated with a burn incurred within facility	Hospital-Acquired Condition
Death/disability associated with a fall within facility	Hospital-Acquired Condition
Death/disability associated with use of restraints within facility	

Criminal Events	
Impersonating a heath care provider (*i.e.,* physician, nurse)	
Abduction of a patient	
Sexual assault of a patient within or on facility grounds	
Death/disability resulting from physical assault within or on facility grounds	

The final rule will appear in the August 19 *Federal Register* and will generally be effective for discharges on or after October 1, 2008.

For more information, see: www.cms.hhs.gov/AcuteInpatientPPS/